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MAY 2 7 2005

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

OrthoHelix Surgical Designs, Inc.
3975 Embassy Parkway
Akron, Ohio 44333
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Contact Person: Edward A. Kroll
Representative Consultant for
OrthoHelix Surgical Designs, Inc.

Date Prepared: March 31, 2005

Name of Device

MaxLock ™ Small Bone System

Common or Usual Name

Fixation Plates and Screws

Classification Name

Single/Multiple Component Metallic Fixation Appliances and Accessories

Predicate Devices

DePuy 100 Tubular Plate (K920738)
KLS Martin Hand Plating System (K040598)

Intended Use

Repair of osteotomies and fractures of small bones in the hand and feet

Device Description

The Maxlock System includes ten (10) fixation plates and 38 screws. Plates vary in size, number of holes and in configuration. Screws vary in size by diameter and length.

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All plates and screws in the Maxlock System are made from Titanium Ti-6Al-4V ELI Alloy. This material conforms with ASTM F-136 Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

The unique X-Cross Profile and curvature of the plates are intended to better match the patients' anatomy. All edges are beveled to minimize wear on surrounding soft tissue and ligaments. The plates are contourable during surgery, to allow a better fit to the profile of bone. Plate holes are counter-sunk to lower the profile of the screw head and help minimize wear on the surrounding soft tissue and ligaments.

Performance Data

FEA's confirm that the MaxLock System is substantially equivalent to its' predicate devices, and that it meets specified requirements for its' intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 7 2005

Orthohelix Surgical Designs, Inc.
C/o Mr. Edward A. Kroll
Spectre Solutions
5905 Fawn Lane
Cleveland, Ohio 44141

Re: K050868
Trade/Device Name: Maxlock™ Small Bone System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: April 4, 2005
Received: April 6, 2005

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: MaxLock™ Small Bone System

Indications for Use:

The MaxLock Small Bone System is indicated for the repair of osteotomies and fractures of:

- Phalanges of the hands and feet.
- Metacarpals and metatarsals.
- Carpals and tarsal bones.
- The wrist and ankle and,
- Arthrodesis of the hands, wrists, foot and ankle.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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